

## **REMARKS**

### **Formal Matters**

In the specification, the various paragraphs have been amended to correct minor editorial problems.

Claims 48-65 remain in this application. Claim 48 is amended. The Examiner has acknowledged that claims 48-65 would be directed to allowable subject matter provided the Examiner's suggestions are adopted. No new matter is added by the amendments.

Support for the amendments is found throughout the specification, and at least as indicated below:

- Page 3, lines 19-23 - reducing IgE-mediated histamine production;
- Page 1, lines 27-30 - histamine release and other mediators results in anaphylaxis.
- Page 12, lines 7-9; Page 54, lines 25-28; Page 55, lines 1-4 - preventing IgE-mediated disorders.

Applicants explicitly reserve the right to pursue unclaimed subject matter in subsequent prosecution.

### **Rejection Under 35 U.S.C. § 112, Second Paragraph**

Claims 48-65 are rejected under 35 U.S.C. § 112, second paragraph, allegedly for being non-enabling for a method of preventing the onset of IgE-mediated disorders.

Specifically, while the Examiner has acknowledged that the specification is enabling for a method of prophylactically administering a humanized anti-IgE antibody that reduces the onset of IgE-mediated disorders, it allegedly does not enable a method of administering at anytime that prevents the onset of IgE-mediated disorders. Specifically, the Examiner asserts that "prevents" implies that therapeutic administration of anti-IgE antibodies is efficacious in each and every patient, but the teachings of Leung *et al.* demonstrate that not all patients receiving prophylactic

administration fail to demonstrate at least some IgE-mediated symptoms when challenged with peanut allergens.

In response, Applicants respectfully disagree that the specification does not enable a method of preventing the onset of IgE-mediated disorders. The term "prevent" appears throughout the specification in juxtaposition with treating. For example, page 12, lines 7-9, page 54, lines 25-28 and page 55, lines 104. However, it appears that Examiner's concern is with the clinical data reported in Leung which reports that each and every patient who was administered anti-IgE therapy failed to exhibit IgE-mediated symptoms upon allergy challenge. Applicants respectfully submit that one of ordinary skill would interpret "prevent" as meaning the cessation in at least one, but perhaps not all patients. A reasonable extrapolation of the Leung *et al.* data also supports that complete cessation of any IgE-mediated symptom is likely to be a function of both the therapeutic dose administered and the quantity of provoking antigen. The logical extension of the Examiner's absolutist reasoning would permit any claim to a therapeutic method of treatment to be disallowed upon the showing of at least one patient for whom the therapeutic was not efficacious, despite an overwhelming showing of many patients in whom therapeutic benefit was shown. Clearly, this would be an absurd result.

However, in light of the Examiner's kind suggestion of enabling subject matter, and in light of the fact that "reducing the onset" clearly covers Applicants' intended interpretation of "prevent" as indicated above (one patient v. all patients), as well as the fact that at least in a therapeutic sense "preventing" is essentially "reducing" to the ultimate degree, and in the interests of expediting prosecution, Applicants hereby amend the claims consistent with the Examiner's suggestion. Applicants retain the right to pursue any effectively surrendered subject matter in subsequent prosecution.

Pursuant to 37 C.F.R. § 1.116 (b)(1), Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 48-65 under 35 U.S.C. § 112, second paragraph in light of compliance with the Examiner's explicit requirements.

Appl. No. 10/791,619  
Amend. dated April 18, 2006  
Response to Office Action mailed on: February 22, 2006

Patent Docket P1123R1D1C1

**SUMMARY**

Claims 48-65 are pending in the application.


If in the opinion of the Examiner, a **telephone conference** would expedite the prosecution of the subject application, the Examiner is **strongly encouraged** to call the undersigned at the number indicated below.

This response/amendment is submitted with a transmittal letter. In the unlikely event that this document is separated from the transmittal letter or if fees are required, applicants petition the Commissioner to authorize charging our Deposit Account 07-0630 for any fees required or credits due and any extensions of time necessary to maintain the pendency of this application.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,  
GENENTECH, INC.

Date: April 18, 2006

By:   
Craig G. Svoboda  
Reg. No. 39,044  
Telephone No. (650) 225-1489

203388